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| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/608,915                      | 06/27/2003  | Stephen L. Hoffman   | ABIOS.023A          | 7068             |
| 20995                           | 7590        | 11/22/2005           | EXAMINER            |                  |
| KNOBBE MARTENS OLSON & BEAR LLP |             |                      | WHALEY, PABLO S     |                  |
| 2040 MAIN STREET                |             |                      | ART UNIT            |                  |
| FOURTEENTH FLOOR                |             |                      | PAPER NUMBER        |                  |
| IRVINE, CA 92614                |             |                      | 1631                |                  |
| DATE MAILED: 11/22/2005         |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/608,915

Applicant(s)

HOFFMAN ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 85-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 85-108 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

***ELECTION/RESTRICTIONS***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

**Group I:** Claims 85-89, 90-92, 107, and 108 drawn to methods for assessing the binding affinity between a candidate peptide and a target protein, classified in class 703, subclass 011. If this Group is elected, then the below summarized specie election is also required. Also, if this Group is elected, then the below summarized specie election is also required.

**Group II:** Claims 93-102 drawn to a method of predicting the binding strength of a candidate peptide for a target protein, classified in class 703, subclass 011. If this Group is elected, then the below summarized specie election is also required. Also, if this Group is elected, then the below summarized specie election is also required.

**Group III:** Claim 103 drawn to a method for generating an epitope useful in the treatment of cancer, classified in class 702, subclass 019. If this Group is elected, then the below summarized specie election is also required.

**Group IV:** Claim 104 drawn to an iterative multiple alignment method of predicting the relative binding affinity of a peptide for a MHC protein classified in class 703, subclass 011.

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**Group V:** Claims 105 and 106 drawn to methods based on letter frequency and  $X^2$  statistical significance tests for predicting the relative binding affinity of a peptide for a MHC protein, classified in class 703, subclass 011.

The inventions are distinct and divergent, each from the other because of the following reasons:

The invention of **Group III** is unrelated to **Groups [I, II, IV, and V]**. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group III and Groups [I, II, IV, and V] have different functions. Group III is drawn to a method for generating an epitope useful in the treatment of cancer. Critical features of Group III that are distinct from Groups [I, II, IV, and V] include the limitation of producing or isolating a protein the comprises said epitope useful in the treatment of cancer. Groups [I, II, IV, and V] do not disclose such limitations.

The inventions of **Group I** are unrelated to **Group II**. In the instant case the different inventions of Group I and Group II have different functions. Group I is drawn to methods for assessing the binding affinity between a candidate peptide and a target protein, whereas Group II is drawn to a method of predicting the binding strength of a candidate peptide for a target protein. Critical features of Group I that are distinct from Group II include the limitation of normalizing first and second affinities to votes for obtaining scores reflecting overall affinity of candidate peptides. Critical features of Group II that are distinct from Group I include the limitation of separating a list into a R1, R2, and R3 rankings, where these ranking are defined as a point in a list relating to various measures of binding strength (i.e. IC values).

The inventions of **Group IV** are unrelated to **Group V**. In the instant case the different inventions of Group IV and Group V have different modes of operation. Group IV is drawn to an

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iterative multiple alignment method of predicting the relative binding affinity of a peptide for a MHC protein, whereas Group V is drawn to methods based on letter frequency and  $X^2$  statistical significance tests for predicting the relative binding affinity of a peptide for a MHC protein. Critical features of Group IV that are distinct from Group V include the use of iterative multiple alignment methods for building profiles by adding new sequence data, whereas frequency based methods split sequence clusters into sub-clusters, and positional methods derive information from peptide positions.

The inventions of **Groups [I and II]** are unrelated to **Groups [IV and V]**. In the instant case the different inventions of Groups [I and II] and Groups [IV and V] have different modes of operation. Groups [I and II] are drawn to methods for assessing the binding affinity between a candidate peptide and a target protein, and predicting the binding strength of a candidate peptide for a target protein, whereas Groups [IV and V] are drawn to methods for predicting the relative binding affinity of a peptide for a MHC protein. Critical features of Groups [I and II] that are distinct from Groups [IV and V] including the limitations of linear, non-linear, and weighted affinity scaling. Groups [IV and V] do not disclose such limitations.

Thus, the search for Groups I, II, III, IV, and V together would present an undue search burden as they are directed to methods that are generally distinct and separate.

### ***SPECIE ELECTION REQUIREMENT***

This application contains claims directed to patentably distinct and divergent species of the claimed inventions. If Group I, II, or III is elected, the applicant is further required to make the following specie elections for purposes of examination. The applicant must elect three of the following species (i.e. Specie I, Specie II, and Specie III):

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**Specie I:** Method as set forth in Group I, II, or III, wherein said epitope is composed of one of the following: (i) sugars, (ii) lipids, or (iii) amino acids.

**Specie II:** Method as set forth in Group I, II, or III, wherein said profile-based scoring uses a clustering heuristic selected from one of the following: (i) iterative multiple alignment, (ii) letter frequencies, or (iii) positional dependencies reflected by two sets.

**Specie III:** Method as set forth in Group I, II, or III, wherein said profile-based scoring employs a principle selected from one of the following: (i) dimensionality reduction, (ii) multiple intra-allelic motifs, or (iii) anchor selection.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Claims 85-103 and 107** are generic to the above species. Specie I is drawn to chemically different species, for which binding reactions are evaluated using distinct techniques. Specie II is drawn to separate and distinct clustering heuristic methods that can be utilized with profile-based candidate peptide scoring. For example, iterative multiple alignment methods build profiles by adding new sequence data, whereas frequency based methods split sequence clusters into sub-clusters, and positional methods derive information from peptide positions. Similarly, Specie III employs profile-based scoring methods drawn principles of dimensionality reduction, multiple intra-allelic motifs, and anchor selection. The bodies of literature that describe Specie I, II, and III are not coextensive. Thus, the search for all species together would present an undue search burden as they are directed to separate divergent subject matter.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct and divergent, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Because these inventions are distinct and divergent for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the inventions to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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 11/5/05  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**